

REMARKS

Formalities

Claims 1-19 are all the claims currently pending in the present Application.

With the current Office Action, the Examiner returns the signed and initialed copies of the Form PTO-SB-08 submitted with Applicants' IDS of June 1, 2005.

Allowable Subject Matter

Claims 17 and 19 are allowed, and the Examiner indicates that Claims 9-11 includes allowable subject matter and would be allowed if rewritten into independent form, including the limitations of the claims from which they depend. Applicant respectfully requests that the rewriting of these claims be held in abeyance at this time.

Claims Rejections

Claims 1-4 and 12-18 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Portney, U.S. Patent Publication No. 2003/0199976 ("Portney"). Claims 5-7 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Portney, in view of Brady et al., U.S. Patent Publication No. 2003/0144733 ("Brady"). Claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Portney, in view of Achatz et al., U.S. Patent No. 4,813,955 ("Achatz").

Claims 1-4 and 12-18, Portney. Applicant respectfully traverses the Examiner's rejection of Claims 1-4 and 12-18 over Portney.

Portney teaches a light refracting principle that is reliant on the presence of step-like transition zones located anywhere in a Fresnel lens, including at the periphery of the lens.

Portney specifically teaches that light refracted from flat Fresnel zone step surfaces causes glare in the eye of the individual in which the IOL is implanted (Para. [0020]).

It is well known by those skilled in the art that the Fresnel lens, the focus of Portney's disclosure, is considered an inferior lens for use as an IOL, and therefore, IOLs that are not constructed using Fresnel principles exist and are adopted in the art. The phenomenon of peripheral light focusing, refers to focusing by the anterior eye of oblique light from the extreme (usually temporal) periphery of the field of view. It utilises off-axis optics and is not well recognised. It was first described by the present inventor and has been referred to as the "Coroneo effect" (*see* Coroneo MT. "Albedo concentration in the anterior eye: a phenomenon that locates some solar diseases" Ophthalmic Surg. 1990 Jan; 21(1): 60-6; Coroneo M.T et al. "Peripheral light focusing by the anterior eye and the ophthalmohelioses" Ophthalmic Surg. 1991; 22: 705-711 and Coroneo MT. "Pterygium as an early indicator of ultraviolet insolation: a hypothesis" Br J Ophthalmol. 1993 Nov; 77(11): 734-9. Review.), and, importantly, occurs independently of the transition zones in a Fresnel lens, as this phenomenon has been observed to occur with the naturally occurring crystalline lens, as well as with a variety of IOLs used in the art including non-Fresnel IOLs. The present inventor has shown that peripheral light focusing is due to the convexity of the cornea which can concentrate light by up to twenty times affecting the distal cornea and lens.

Subsequent to this work, the present inventor now shows that peripheral light focusing occurring in a patient with a IOL results in visual disturbances that include glare, streaks and dark shadows in the temporal visual field. Specifically, peripheral light focusing results in

extreme oblique incident light, such as 65-89°, to be intensified by approximately 2.5 times and focused on the nasal retina. Focused beams of light result in foci in the nasal retina producing visual disturbances including visual effects in the temporal visual field (*see* Example 2), i.e. at the periphery of the human visual field, as experienced by patients with an IOL.

Thus, the teaching of Portney is completely unrelated to that of the present invention. Portney describes incident light creating glare, relying on a definition of glare as “*any degree of light falling on the retina in excess of that which enables one to see clearly*” and “*Any excess of light which hinders rather than helps vision. (Too much light in the wrong place)*” at paragraph [0011]. Therefore, Portney is concerned with excess light entering the eye, and the poor vision associated with it in the presence of a Fresnel lens. Portney is not concerned with the convexity of the cornea, and does not teach that due to peripheral light focusing, oblique incident light as taught by the present invention will be intensified approximately 2.5 times the incident intensity (*see* Example 1) and projected onto the temporal retina causing photic disturbances in the temporal visual field.

Moreover, the intraocular lens of the present invention, in accordance with the rejected claims, is configured to reduce or eliminate oblique incident light photic disturbances in the eye caused by focusing of oblique incident light that is, oblique incident light as taught by the disclosure of the specification.

Therefore, Portney does not teach or suggest the phenomenon upon which the present invention, in accordance with the rejected claims, is based, nor does it teach or suggest an explanation for photic disturbances in the temporal visual field. Consequently, Portney does not

teach an intraocular lens that addresses the subject matter of the present invention, i.e. unexpected photic disturbances encountered following the replacement of the natural crystalline lens with an intraocular lens.

Applicant draws the Examiner's attention to Figure 17 of Portney and its comparison with Figure 3 of the instant specification which illustrates the optic principles involved in peripheral light focusing. Figure 17 of Portney deals with parallel beams of light striking the IOL from the near, rather than extreme periphery. In Figure 3 of the instant specification, it can be seen that rays of light from the extreme periphery are focused by the cornea onto the IOL and are CONVERGING rather than parallel when they strike the IOL, i.e. they are intensified, and this is why the induced foci are so bothersome to patients. Oblique rays striking temporal limbus (T) (corneal location) are converged by the limbal convexity to intense foci on the nasal side (N) of the eye. In this bundle of rays (as shown incident at an 80-degree angle to the visual z-axis), many bypass the front of the IOL optic to form focal area 1 while the rest strike the front surface of the IOL optic and are refracted to form focal area 2. Note the penumbra between the 2 foci. Thus, the optic principle relied upon by Portney involves parallel rays of light incident on the flat surface of a Fresnel lens transition zone, as shown in Figure 17, whereas the present invention, in accordance with the rejected claims, teaches the phenomenon of convergence, focusing and intensification of extreme oblique incident rays of light, i.e. peripheral light focusing.

Applicant submits that based on the very different teaching of the present invention, in accordance with the rejected claims, as compared to that of Portney, Portney cannot anticipate the rejected claims, such as Claim 1, which provides an intraocular lens configured to reduce or

eliminate oblique incident light photic disturbances in the eye due to peripheral light focusing, as defined in Claim 1 (line 6). Applicant respectfully requests, therefore, reconsideration and withdrawal of the rejection of Claims 1-4 and 12-18 over Portney.

Claims 5-7, Portney and Brady. Applicant respectfully traverses the Examiner's rejection of Claims 5-7 over Portney and Brady.

The Examiner asserts that Brady has been relied upon merely as prior art teaching the use of light absorbing materials to help reduce glare.

It appears that the Examiner has failed to appreciate that the person skilled in the art, in addition to having read Brady, is also likely to be in possession of further knowledge, by way of reading the prior art submitted with Applicant's IDS of June 1, 2005, that teaches away from Brady, i.e. that teaches that the measures adopted by Brady do not overcome dysphotopsia. The Examiner appears to argue that a person skilled in the art could consider the disclosure by Brady only in relation to light absorbing materials, ignoring the functionality of the lens despite other relevant prior art teaching the ineffectiveness of the Brady lens. Applicant submits that based on the fact:

(i) that Portney does not teach the principle upon which the present invention, in accordance with the rejected claims, is based, and therefore does not address the same problem as that described in the present specification, and

(ii) that the lenses described by Brady are already known in the art to not overcome photic disturbances, and that therefore, the measures adopted therein alone do not solve the problem,

Applicant respectfully submits that the person skilled in the art could not possibly be motivated towards the present invention, in accordance with the rejected claims, by combining the teachings of Portney and Brady. Applicant respectfully requests, therefore, reconsideration and withdrawal of the rejection of Claims 5-7 over Portney and Brady.

Claim 8¹, Portney and Achatz. Applicant respectfully traverses the Examiner's rejection of Claims 8 and 9 over Portney and Achatz.

The Examiner asserts that both Portney and Achatz teach IOL's with segmented zones and that by providing a zone closer to the wearers nose as taught by Achatz and the curvatures as taught by Portney it is possible to refract oblique incident light to the forward position of the nasal retina in the eye.

Applicant respectfully disagrees with the Examiner's rationale for combining the disclosure of these citations.

Applicant draws the Examiner's attention to the fact that Achatz does not teach a particular advantage in placing the "near" zone of the lens closer to the wearer's nose, as described at column 3, lines 62-64, and in Figure 3. This is because Achatz also describes a lens having a greater number of near and far zones defined by sectors disposed alternatively around the lens axis. This configuration is shown in Figure 4 illustrating that the near zone will be disposed both near the wearer's nose and remotely from the wearer's nose (or temporally). Therefore, Applicant submits that Achatz does not in fact teach that the near zone is advantageously placed near the wearer's nose. Achatz does not provide any other disclosure in

¹ As indicated by the Examiner, Claim 19 is allowed (Office Action, p.4).

relation to alignment of a zone with a wearer's nose. Moreover, Achatz is merely describing multiple variations in the location of alternating zones with no one embodiment being singled out as being optimum for any particular reason.

Accordingly, Achatz could not impart any motivation to one of skill in the art to specifically select a configuration having a nasally aligned zone so as to advantageously combine it with the teaching of Portney, which as stated previously does not address the phenomenon of peripheral light focusing and the resultant visual disturbances. The Examiner has failed to indicate why one of skill in the art would consider this particular zone configuration as bringing any benefit in light of the disclosure by Portney. Moreover, Portney does not teach that peripheral light focusing causes oblique incident light to strike the nasal perimeter of the intraocular lens and thereafter be focused onto sites in the nasal interior of the eye, including the nasal retina causing photic disturbances. This principle is not taught by Portney, but only by the present inventor at page 4, lines 15-18 of the specification. As this information is not disclosed by Portney or by Achatz, and Achatz does not teach the significance of the nasal retina in producing photic disturbances by oblique incident light, Applicant respectfully submits that the Examiner's rationale is not correct. Applicant submits that the disclosure of Achatz is not relevant to the teaching of the present invention, and therefore respectfully request reconsideration and withdrawal of the rejection of Claim 8 over Portney and Achatz.

New Claim 20

With this Amendment, Applicant adds new Claim 20 in order more fully to cover various aspects of Applicant's invention as disclosed in the specification. Claim 20 is supported in the

originally-filed specification at least at the paragraph beginning on page 4, line 15. Applicant respectfully submits that Claim 20 is patentable at least by virtue of its dependence on Claim 1.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Laura Moskowitz
Registration No. 55,470

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: February 6, 2006